

malodon

**Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000**

May 21, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Austin R. Smith
9200 West 8570 North
Lehi, UT 84043

Ref. # DEN-99-07

Dear Mr. Smith:

PURGED

An investigation at your cattle operation located in Lehi, Utah, was conducted by Consumer Safety Officer Margaret M. Annes. The inspection confirmed that you offered an animal for sale for slaughter as food, in violation of sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you may have caused animal drugs to become adulterated within the meaning of section 501(a)(5) of the Act.

On June 5, 1998, you offered a beef cow, identified as USDA case number 98-0469-UT, for slaughter as human food to [REDACTED]. USDA analysis of kidney tissue samples collected from this animal identified the presence of gentamicin residue of [REDACTED] ppm. No tolerance has been established for residues of gentamicin in the edible tissues of beef cows in Title 21 Code of Federal Regulations Part 556.300 (21 CFR 556.300) at the time the analysis was conducted.

Our investigation revealed the use of $\text{L} \times \times \text{J}$ (Gentamicin Sulfate Solution). The presence of this drug in edible tissue from this animal causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals under conditions which are so inadequate that diseased and/or medicated animals bearing potentially harmful drug residues may enter the food supply. For example, you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions are adulterated within the meaning of section 402(a)(4) of the Act.

You are adulterating the drug brand of Gentamicin Sulfate Solution that your firm uses on beef cows within the meaning of section 501(a)(5) of the Act when you fail to use the drug in conformance with its approved labeling. There is no labeled use of in beef cattle. Your use of the drug without following the labeling causes the drug to be unsafe for use.

We acknowledge receipt of your father's letter, dated January 20, 1999, addressed to Margie Annes, Investigator, Salt Lake City Resident Post. In the letter, your father states that he instructed you to inject the downed cow with gentamicin and that he failed to advise you of the need to withhold the animal from slaughter until the drug was

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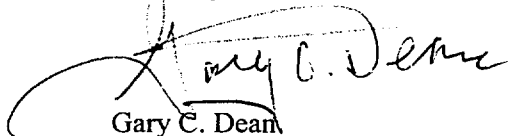
eliminated from edible tissues. Notwithstanding this admission, as a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law. Failure to do so may result in regulatory action without further notice such as seizure, and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of the steps you have taken to bring your operation into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be sent to H. Tom Warwick, Compliance Officer, Food and Drug Administration, P.O. Box 25087, Denver, Colorado, 80225-0087. He may be reached at (303) 236-3054 if you have any questions about this matter.

Sincerely,


Gary C. Dean
District Director

enclosure: 21 CFR 530

cc: Mr. Ronald K. Jones, D.V.M.
Boulder District Manager
USDA/FSIS
665 S. Broadway, Suite B
Boulder, CO 80303

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9200 West 8570 North
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